5/1/00 NRG

HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M3690N

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-49

April 27, 2000

Michael A. Blesy, Owner
M Blesy Dairy
17255 SE Hwy 452
Umatilla, FL 32784

Dear Mr. Blesy:

An investigation of your dairy farm located at 17255 S.E. Hwy. 452, Umatilla, FL conducted by our investigator Melissa J. Hill on February 29, March 7, 8 and 14, 2000, confirmed that you offered an animal for sale for slaughter as food in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about February 2, 2000 you sold a dairy cow, identified by ear tag number 5305, back tag #56HB0583 and USDA sample number 404436 for slaughter as human food by [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of Penicillin in the liver of the animal at a level of .90 ppm and in the kidney at a level of .38 ppm. A tolerance of 0.05 ppm has been established for residues of Penicillin in the edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are inadequate to ensure that diseased animals and/or medicated animals bearing potentially harmful drug residues are prevented from entering the food supply. Specifically, you fail to keep medication records which identify the amount of drug administered and adherence to the proper withdrawal time to permit depletion of potentially hazardous residues from the edible tissues. You also fail to maintain drug inventory records. Food from animals held under these conditions is adulterated.

You are adulterating the drug Penicillin G Procaine Aqueous Suspension that your firm uses on dairy cattle within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug without following the labeled withdrawal period causes the drug to be unsafe to use.

This letter is not intended to be an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse in another state is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrections cannot be completed within (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Kendall W. Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

Edward R. Atkins

Edward R. Atkins
Acting Director
Florida District